



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer *et al.*

Serial No.: 10/087,388

Filed: 03/01/02

Entitled: Skin Substitutes For Irritancy Testing

Group No.: 1634

Examiner: Switzer

INFORMATION DISCLOSURE  
STATEMENT TRANSMITTAL

Commissioner for Patents  
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Dated: September 5, 2003

By:

Mary Ellen Waite

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

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Dated: September 5, 2003

J. Mitchell Jones

Registration No. 44,174

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MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
608/218-6900



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Strata-06948  
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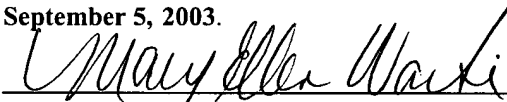
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Mary Ellen Waite

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The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Pat No. 6,074,859;
- U.S. Pat No. 5,968,546;

- U.S. Pat No. 4,485,096;
- U.S. Pat No. 6,039,760;
- U.S. Pat No. 5,536,656;
- U.S. Pat No. 5,989,837;
- U.S. Pat No. 5,994,115;
- U.S. Pat No. 5,693,332;
- U.S. Pat No. 5,658,331;
  
- Sando et al., J. Biol. Chem., 271(36): 22044-51 (1996);
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- Ponc et al., J. Invest. Dermatol., 109(3): 348-55 (1997);
- Denda et al., J. Invest. Dermatol., 111(5): 858-63 (1998);
- Hanley et al., J. Clin. Invest., 100(3): p. 705-12 (1997);
- Hanley et al., J. Invest. Dermatol., 113(5): 788-95 (1999);
- Zhang et al., J. Biol. Chem., 273(28): 17917-25 (1998);
- Anderson and Young, Quantitative Filter Hybridization, in Nucleic Acid Hybridization [1985];
- Smith and Waterman, Adv. Appl. Math. 2: 482 (1981);
- Needleman and Wunsch, J. Mol. Biol. 48:443 (1970);
- Pearson and Lipman, Proc. Natl. Acad. Sci. (U.S.A.) 85:2444 (1988);
- Graham and van der Eb, Virol., 52:456 [1973];
- deWet et al., Mol. Cell. Biol. 7:725 [1987];
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- Schurer et al., Dermatologica, 183: 77-94 (1991);
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- Reichert et al., The cornified envelope: a key structure of terminally

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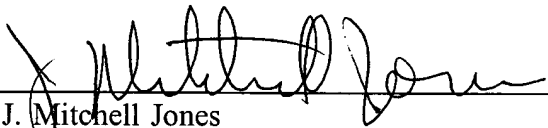
- Sachsenmeier et al., *J. Biol. Chem.*, 271: 5-8 (1996);
- Hines et al., *Promega Notes*, 59: p. 30-36 (1996);
- Hines et al., *J. Biol. Chem.*, 271(11): 6245-6251 (1996);
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- Haake et al., *J. Invest. Derm. Symp. Proc.*, 3: 28-35 (1998);
- Wertz et al., *Chem. Phys. Lipids*, 91(2): 85-96 (1998);
- Meana et al., *Burns* 24:621-30 (1998);
- Baden, *In Vitro Cell. Dev. Biol.* 23(3):205-213 (1987);
- Boucamp et al., *J. cell. Boil.* 106:761-771 (1988);
- Bell et al., *Proc. Nat. Acad. Sci. USA*, 76: 1274-1278 (1979);
- Fusenig, Epithelial-mesenchymal interactions regulate keratinocyte growth and differentiation in vitro, in *The Keratinocyte Handbook*, I.M. Leigh, Lane, E.B., and F.M. Watt, Editor. 1994, University Press: Cambridge (1994);
- Parenteau et al., *Cytotechnology*, 9: 163-171(1992);
- Cumpstone et al., *J. Invest. Dermatol.*, 92(4): 598-600 (1989);
- Ponc, *Int. J. Cosmetic Sci.*, 14: 245-264 (1992);
- Mak et al., *J. Invest. Dermatol.*, 96(3): 323-7 (1991);
- Grubauer et al., *J. Lipid Res.*, 30(3): 323-33 (1989);
- Ponc et al., *J. Invest. Dermatol.*, 109(3): 348-55 (1997);
- Williams et al., *J. Invest. Dermatol. Symp. Proc.*, 3(2): 75-9 (1998).
- Vicanova et al., *J. Invest. Dermatol. Symp. Proc.*, 3(2): 114-20 (1998);
- Aszterbaum et al., *Pediatr. Res.*, 31(4 Pt 1): 308-17 (1992);
- Hardman et al., *Development*, 125: 1541-1552 (1998);
- Segre et al., *Nat. Genet.*, 22(4): 356-60 (1999);

- Zhang et al., J. Biol. Chem., 273(28): 17917-25 (1998);
- Stryer ed., Biochemistry, pg. 17-21, 2nd ed, WH Freeman and Co., 1981;
- Denyer et al., Drug Discov. Today 3:323-32 (1998);
- Gonzales et al., Drug. Discov. Today 4:431-39 (1999);
- Schroeder and Neagle, J. Biomol. Screening 1:75-80 (1996);
- de Brugerolle de Fraissinette et al., Cell Biology and Toxicology, 15:121 [1999];
- Mukaida et al., J. Immunology, 143:1366 [1989];
- Roebuck, J. Interferon Cytokine Res., 19:429 [1999];
- Iyer et al., Science 283:83 [1999];
- Fambrough et al., Cell 97:727 [1999];
- Eisen et al., PNAS 95:14863 [1998];
- Golub et al., Science 286:531 [1999];
- Myers et al., A. J. Surg. 170(1):75-83 (1995);
- Boyce et al., J. Invest. Dermatol., 107(1): p. 82-7 (1996);
- Shields et al., J. Biol. Chem, 271(33): 20009-17 (1996);
- Zhang et al., J. Biol. Chem., 273(28): 17917-25 (1998);
- Geiman et al., Nucleic Acids Res., 28(5): 1106-1113 (2000);
- Mahatan et al., Nucleic Acids Res., 27(23): 4562-9 (1999)).
- Carroll et al., Proc. Natl. Acad. Sci. USA, 90(21): p. 10270-4 (1993);
- Lee et al., J. Biol. Chem., 271(8): 4561-8 (1996);
- Yet et al., J. Biol. Chem., 273(2): 1026-31 (1998);
- Lopez-Bayghen et al., J. Biol. Chem., 271(1): 512-520 (1996);
- Perkins et al., Toxicological Sciences, 48:218 [1999];
- Furutani et al., Nuc. Acid Res. 14:3167 [1986];
- Mori and Prager, Blood 87:3410 [1996];

- Corsini et al., J. Invest Dermatol. 108:892 [1997];
- Elefanty et al., Proc Natl Acad Sci U S A, 95:11897 [1998];
- Morrison et al., Mech Dev, 1999. 84169 [1999];
- Behne et al., J. Invest. Dermatol., 114(1): 185-92 (2000);
- Asbill et al., Pharm. Research 17(9): 1092-97 (2000);
- Allen-Hoffmann et al., J. Invest. Dermatol., 114(3): 444-455 (2000);
- Chang et al., Am J. Respir Cell Mol Biol. 22:502 [2000];
- Abe et al., Am J. Respir Cell Mol Biol., 22:51 [2000];
- Geiman et al., Nucleic Acids Res., 28(5): 1106-1113 (2000);
- Jin et al., Biochem Biophys Res Commun, 270:978 [2000].

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

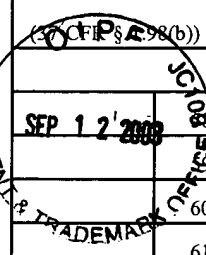
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J. Mitchell Jones  
Reg. No. 44,174  
MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
(608) 218-6900

FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: STRATA-06948		Serial No.: 10/087,388	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use Several Sheets If Necessary)  (37 CFR § 1.98(b))				Applicant: Allen Comer <i>et al.</i>			
				Filing Date: 03/01/02		Group Art Unit:	
U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	6,074,859	6/13/00	Hirokawa <i>et al.</i>	435	189	7/9/98
	2	5,968,546	10/19/99	Baur <i>et al.</i>	424	444	5/15/98
	3	4,485,096	11/27/84	Bell	424	95	5/26/82
	4	6,039,760	3/21/00	Eisenberg	623	15	2/16/96
	5	5,536,656	7/16/96	Kemp <i>et al.</i>	435	240.23	2/9/94
	6	5,989,837	11/23/99	Allen-Hoffmann <i>et al.</i>	435	7.21	7/13/98
	7	5,994,115	11/30/99	Meyers	435	235.1	7/22/97
	8	5,693,332	12/2/97	Hansbrough	424	426	8/11/95
	9	5,658,331	8/19/97	Della Valle <i>et al.</i>	623	15	6/7/95
FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS							
		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation
							Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)							
	10	Sando <i>et al.</i> , J. Biol. Chem., 271(36): 22044-51 (1996)					
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	23	Schurer <i>et al.</i> , Dermatologica, 183: 77-94 (1991)					
	24	Aeschlimann <i>et al.</i> , Thrombosis & Haemostasis, 71(4): 402-15 (1994)					
	25	Reichert <i>et al.</i> , The cornified envelope: a key structure of terminally differentiating keratinocytes, in Molecular Biology of the Skin, M. Darmon, Editor. 1993, Academic Press, Inc.: San Diego. 107-150 (1993)					
	26	Sachsenmeier <i>et al.</i> , J. Biol. Chem., 271: 5-8 (1996)					
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54	Iyer et al., Science 283:83 [1999]				
55	Fambrough et al., Cell 97:727 [1999]				
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		62	Geiman et al., Nucleic Acids Res., 28(5): 1106-1113 (2000)			
		63	Mahatan et al., Nucleic Acids Res., 27(23): 4562-9 (1999)			
		64	Carroll et al., Proc. Natl. Acad. Sci. USA, 90(21): p. 10270-4 (1993)			
		65	Lee et al., J. Biol. Chem., 271(8): 4561-8 (1996)			
		66	Yet et al., J. Biol. Chem., 273(2): 1026-31 (1998)			
		67	Lopez-Bayghen et al., J. Biol. Chem., 271(1): 512-520 (1996)			
		68	Perkins et al., Toxicological Sciences, 48:218 [1999]			
		69	Furutani et al., Nuc. Acid Res. 14:3167 [1986]			
		70	Mori and Prager, Blood 87:3410 [1996]			
		71	Corsini et al., J. Invest Dermatol. 108:892 [1997]			
		72	Elefanty et al., Proc Natl Acad Sci U S A, 95:11897 [1998]			
		73	Morrison et al., Mech Dev, 1999. 84169 [1999]			
		74	Behne et al., J. Invest. Dermatol., 114(1): 185-92 (2000)			
		75	Asbill et al., Pharm. Research 17(9): 1092-97 (2000)			
		76	Allen-Hoffmann et al., J. Invest. Dermatol., 114(3): 444-455 (2000)			
		77	Chang et al., Am J. Respir Cell Mol Biol. 22:502 [2000]			
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